Subject Area:

Evaluation of knowledge, attitude, and practice of adverse drug reactions reporting among doctors and nursing staff of a rural tertiary care teaching hospital of Maharashtra

Sanyukta M. Patil
SMBT IMS & RC

Satish E. Bahekar
Government Medical College, drsatish3683@gmail.com

Follow this and additional works at: https://jmisr.researchcommons.org/home

Part of the Medical Sciences Commons, and the Medical Specialties Commons

Recommended Citation
DOI: https://doi.org/10.4103/JMISR.JMISR_36_18

This Original Study is brought to you for free and open access by Journal of Medicine in Scientific Research. It has been accepted for inclusion in Journal of Medicine in Scientific Research by an authorized editor of Journal of Medicine in Scientific Research. For more information, please contact m_a_b200481@hotmail.com.
Evaluation of knowledge, attitude, and practice of adverse drug reactions reporting among doctors and nursing staff of a rural tertiary care teaching hospital of Maharashtra

Satish E. Bahekar, Sanyukta M. Patil
Department of Pharmacology, Government Medical College, Aurangabad, 1MBBS(III), SMBT IMS and RC, Dhamangaon Ghoti, Igatpuri, Dist. Nashik, Maharashtra, India

Abstract
Context
The adverse drug reactions (ADRs) are of great concern for any health care set ups as they directly or indirectly cost in terms of disability, prolongation of hospital stay, or even death. Hence, regular and timely reporting of ADR is of great importance, especially in treating doctors and nursing staff.

Aims
The main aim of this study was to assess the knowledge, attitude, and practice (KAP) of ADR reporting among doctors and nurses of tertiary care teaching hospital.

Settings and design
This was a prospective, cross-sectional questionnaire-based study that included 50 doctors and 50 nurses from the clinical departments of rural tertiary care teaching hospital.

Patients and methods
A self-developed, prevalidated questionnaire consisting of good mixture of open-ended and close-ended questions was used to obtain data, focusing on KAP of ADR reporting. The filled questionnaires were collected from the participants.

Statistical analysis
The collected data was analyzed using statistical package for the social sciences, version 22.

Results
The results obtained were of mixed nature. But the overall KAP pertaining to ADR reporting was statistically on a higher side in the doctors’ group as compared to nursing staff group.

Conclusions
The study reveals that both doctors and nursing staff are aware of ADR reporting; their attitude toward ADR reporting is right, but it is not reflected when it comes to actual reporting. The issues related to under reporting and lack of knowledge about the reporting system are clearly evident. Hence, creating an awareness on ADR reporting and sensitizing can aid in improving spontaneous reporting.

Keywords: Adverse drug reactions, pharmacovigilance, spontaneous reporting

INTRODUCTION
Adverse drug reactions (ADRs) are currently of major significance because of their higher incidence on a global front. According to the WHO ADR is defined as ‘any noxious change that is suspected to be due to a drug, occurs at doses normally used in man, requires treatment or decrease in dose, or indicates caution in the future use of the same drug’ [1]. ADRs are usually associated with significant morbidity and mortality.
and have a major impact on public health. ADRs are common occurrences in daily practice of medical professionals and most of them can be tackled, and are manageable [2]. Studies have shown that ADR reporting is poor among the health care professionals, particularly in developing countries [3]. It is very essential to identify and prevent the occurrence of ADRs by taking preventive measures as mentioned in the Pharmacovigilance Program run by Government of India. Pharmacovigilance has been defined by the WHO as the ‘science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem’ [1]. Its key objectives are to enhance patient care and safety in relation to the use of medicines; reckon the benefits, harm, and effectiveness of the medication and facilitate report the safety of the drug to health care professionals and the community’ [4]. When a drug is approved by the Food and Drug Administration, there is little known about the serious and rare ADRs associated with the drug. In contrast, postmarketing surveillance is also essential and relies mostly on the voluntary ADR reporting by health care professionals [5]. The fact that voluntary reporting is easily accessible to every medical professional, and its judicious use will decline the incidence of ADRs is less known to many of them, and hence under reporting is on a higher level. Other reasons for under reporting include the lack of awareness of the reporting method and the forms available for reporting, as well as the belief that they are not obliged to report an ADR [6]. In many countries, including India, pharmacovigilance system is operational; however, under reporting is a major problem. Under reporting of ADRs is widespread and poses a daunting challenge in pharmacovigilance. Globally 95% of the ADRs do not get reported [7,8]. A study conducted by Ramesh et al. [9] in South India, observed that 0.7% of the hospital admissions were due to ADRs, and ~3.7% of the patients admitted experienced an ADR, out of which 1.3% were lethal. WHO started an ADR monitoring center in Uppsala, Sweden and India became an integral part of it in 1997, but the major obstacle in monitoring was under reporting. Various studies have demonstrated that new adverse reactions are discovered effectively from voluntary reporting by health care professionals than from other methods, including large scale postmarketing studies [10]. In fact, spontaneous ADR reporting system is an important method for monitoring of ADRs owing to cost-effectiveness and the ease of detection of suspected and serious ADR, especially during postmarketing surveillance [11]. The ADR reporting and monitoring is of great importance to understand the trends in adverse reactions and to prevent the harmful effects suffered by the patients [12]. Doctors and nurses are the principal health care professionals who can effectively report the ADRs as they are consistently associated with the out patient department and in patient department, thereby helping in improvising the existing practices. Connotatively, nurses play a vital role in spontaneous reporting of ADRs [13]. Hence, it is of utmost importance that the culture of ADR reporting must be inculcated in a positive manner in these two groups, in particular. Knowledge, attitude, practice (KAP)-based studies in the hospital settings can prove as an important tool to reduce under reporting of ADRs. The main aim of this study was to assess the KAP of an ADR reporting among doctors and nurses, indirectly pointing to the extent of awareness. Currently, there is a lack of comprehensive reporting system in our country and hence, it becomes very important to have a conducive system that would devise appropriate ways to handle the ADRs [14]. As the study was carried out in a rural area, where the patients particularly are unaware about the effectiveness of medication prescribed to them; therefore it becomes all the more important to report any reaction and devise ways to tackle it. This study will serve as a preliminary approach towards the above mentioned objectives of motivating the health care professionals and making advances in the existing scenario.

**Patients and methods**

The study was conducted in a rural tertiary care teaching hospital located in Northern Maharashtra over a period of 2 months.

This was a prospective, cross-sectional questionnaire-based study that included 50 doctors and 50 nurses from various clinical departments. The Institutional Ethics Committee granted approval for the study and written informed consents were sorted out from the participants. During the entire course of this study, strict confidentiality was maintained and there were no divulsion of any details.

The instrument for this study was a self-developed, prevalidated questionnaire consisting of both open-ended and close-ended questions. It focused mainly on the three domains of this study – KAP. The factors explored were the knowledge of the respondents, their level of awareness, as well as their attitudes about ADRs and ADR reporting, and the practices pertaining to spontaneous reporting. The questionnaires were distributed to the participants with prior explanation of the objectives of this study and then they were asked to fill them and hand it over within 24 h. A total of 100 questionnaires were distributed and all were returned back within the stipulated duration. The collected data was analyzed using statistical package for the social sciences, version 22 (IBM Corporation North Castle Drive Armonk, NY 10504-1785 U.S.A.).

**Results**

The study was conducted with the help of a prevalidated questionnaire containing both open-ended and closed-ended questions and the results obtained can be summarized as follows.

The questionnaire consisted of 13 questions, out of which two were subjective questions to assess the knowledge about ADRs, and the rest of them were objective type. They aimed at comparing, as well as assessing the KAP of the health care professionals on ADR reporting. In most of the questions,
the respondents had the liberty to give multiple answers to a single question. The first two questions were purely subjective to test the knowledge of the participants about the ADRs (definition and types) and as we assessed the results, it was found that the doctors had better knowledge regarding them.

Thus, 78% of the doctors were aware about a drug/drugs banned in India due to the ADRs, whereas 88% of the nurses responded with a negative answers (Fig. 1). In doctors, 48% of them were aware about the existence of the institutional ADR reporting system, whereas only 34% of the nurses were aware about it (Fig. 2). About 86% of the doctors said that they encountered 0–5 ADRs per week, on the contrary, 82% of the nurses were of the opinion that they encountered 5–10 ADRs per week (Fig. 3).

In nurses, 48% of them thought that ADR reporting was important, whereas others felt that it was not very important. Half of the nurses and 88% of the doctors were of the opinion that it is important to report them (Fig. 4). On questioning about the importance of ADR reporting, the responses we got were quite varied, 16% of the doctors and 17% of the nurses thought that it was appropriate to detect new ADRs, 45% doctors and 29% of the nurses thought that the patient safety was important, 26% of the doctors and 25% of the nurses were of the opinion to tackle the future ADRs, 7% of the doctors and 11% of the nurses thought that it was necessary to measure the incidence of ADRs, and 5% of the doctors and 11% of the nurses thought that the global sharing about ADRs is the need of the hour (Fig. 5). When asked about the important factors that determine a reporting process, they had mixed views, 40% of the doctors and 48% of the nurses were of the opinion that severity is an important determinant, 31% of the doctors and 20% of the nurses thought that unusualness of the reaction was one of the factor (Fig. 6), 37% of the doctors and 29% of the nurses were of the opinion that lack of awareness about the reporting process could be a factor, whereas 15% of the nurses and 13% of the doctors had the fear of professional liability, which could be the reason for under reporting (Fig. 7). On questioning about the types of ADRs that should be reported, they had the following answers – 38% of the doctors and 53% of the nurses thought that all sort of ADRs must be reported, whereas 19% of the doctors and 27% of the nurses felt that only serious and life threatening ADRs must be reported (Fig. 8); 63% of the doctors and 35% of the nurses were of the opinion that doctors should report the ADRs, whereas 17% doctors and 27% nurses thought that nurses should report the ADRs (Fig. 9); 59% of the doctors and 18% of the nurses had reported ADRs in their practice (Fig. 10). On enquiry, where they had reported the ADRs, 39% of the doctors and 13% of the nurses reported in the institutional ADR reporting center. In contrast, 12% doctors and 4% nurses reported in the ADR reporting center of some other institute (Fig. 11). On assessing their attitude towards reporting, 79% of the doctors and 61% of the nurses felt that ADR reporting should be made compulsory; 12% doctors and 4% nurses reported that the ADRs must be enumerated; and 8% of the doctors and 4% of the nurses were of the opinion that it should be voluntary from the health care professionals’ side without any undue compulsion (Fig. 12).
DiscussIon

The Pharmacovigilance Program of India was launched in India in the year 2010 with a major goal to safeguard the health of people. But for its effective functioning well-coordinated approaches are required from the health care professionals in reporting the adverse effects, as well as the sensitization and the cognizance about the program, which sadly is lacking in the country. The ADRs are particularly harmful, in recent years, as there have been incidences of high fatality rate due to some of them. A study by Lazraou et al. [15], described ADRs to be the fourth to sixth largest cause of death in the United States. Thus, ADRs bestow significantly to the burden of a disease by causing drug-related hospital admissions, prolonging the hospital stay, plus increasing the visits to emergency wards [16]. From the study above, we could gauge that the awareness among doctors was more than the nursing staff, but still there are loopholes in the way of accepting this fact, and to move forward and report ADRs.

Figure 5: What is the importance of ADR reporting? ADR, adverse drug reaction.

Figure 6: In your opinion, what are the important factors to decide whether the ADR should be reported or not? ADR, adverse drug reaction.

Figure 7: What are the factors that are responsible for under-reporting?

Figure 8: In your opinion, what sort of ADRs must be reported? ADR, adverse drug reaction.

Figure 9: In your opinion, who should report ADRs? ADR, adverse drug reaction.

Figure 10: In your practice, have you ever reported any ADR? ADR, adverse drug reaction.

to the burden of a disease by causing drug-related hospital admissions, prolonging the hospital stay, plus increasing the visits to emergency wards [16]. From the study above, we could gauge that the awareness among doctors was more than the nursing staff, but still there are loopholes in the way of accepting this fact, and to move forward and report ADRs. Around 59% of the doctors had reported ADRs compared to just 18% of the nursing staff, emphasizing the need to create better interventional practices in motivating reporting. The study even portrayed that the causes of under reporting varied, but the most common cause was the lack of awareness about the reporting process. Since, the study was conducted in a rural setup, so it might be that the ADRs experienced by the patients were not largely reported due to lack of caution among the patients to notify the doctor about any sort of bizarre reactions and hence, the under reporting. In contrast, the knowledge about the existence of ADR reporting center in the institute was not so satisfactory when compared to the under reporting. On a positive note, towards the end of the questionnaire,
maximum number of the health care professionals thought that ADR reporting should be made compulsory keeping in mind the patient’s safety. The study revealed that there was a tremendous gap in proficiency to report an ADR among the doctors and the nurses, primarily due to the less sentence about the Pharmacovigilance Program of India or because of lack of proper knowledge on how to detect an ADR at the earliest, as well as to report it to the concerned doctor or the institutional ADR reporting system. This problem can be solved up to a satisfactory level by many measures. Most importantly, through educational interventions, implementation to upgrade the knowledge, thereby changing their attitude towards reporting [17, 18].

Our study had certain limitations, such as it was conducted in a rural hospital set up, hence these results cannot be made generalized for those in the urban areas. Sample size was also less, but it was taken according to the available number of employees currently with us and for proper comparison. We included nurses in this survey so that a differentiating group could be used to compare the KAP of the health care professionals. The results were quite similar, but the most surprising fact to fathom was that the awareness among the professionals. The results were quite similar, but the most surprising fact to fathom was that the awareness among the doctors was not at par with their practices or experiences and, hence, it is high time to encourage both of the study groups in taking concrete measures to reinforce the reporting system.

Conclusions
To conclude, these types of preliminary studies may prove useful in devising strategies to create awareness in reporting of ADRs among health care professionals working in close relationship with clinical set ups. However, regular awareness programs are very much essential to sensitize health care professionals to improve on the current practice of pharmacovigilance. It can also be emphasized that good co-ordination among doctors and nursing staff can play a vital role in promoting the rational and safe use of medicines.

Acknowledgements
The authors acknowledge with gratitude the support they got from the college and hospital management for permission and all the necessary help for conducting this study. The authors also thank Mr Jagdish Pawar, statistician from the Department of Community Medicine, for helping the authors in the statistical aspects of this study.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

References